UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

JOSEPH BARONE,	:	
	:	Index No. 6:17-cv-06877
Plaintiff,	:	
-against-	:	
BAUSCH & LOMB, INC., MORCHER GmbH, and FCI OPHTHALMICS, INC.,	:	
Defendants.	:	

PLAINTIFF'S RESPONSE
TO DEFENDANT'S NOTICE OF SUPPLEMENTAL AUTHORITY

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Plaintiff hereby responds to defendant Bausch & Lomb, Inc.'s notice of supplemental authority, i.e. *Conklin v Medtronic*, No CV-17-0322-PR, slip op. (Ariz. Dec. 18, 2018).

In its notice, defendant makes the preposterous assertion that "after the decision in *Conklin*,… *Rosen*… can no longer be considered good law." In other words, defendant is arguing that because the Supreme Court of the State of Arizona ruled that Arizona common law does not impose a duty upon a manufacturer to submit adverse event reports to a government agency, it somehow follows that the Northern District of New York's holding regarding New York common law in *Rosen v. St. Jude Med., Inc.,* 41 F. Supp. 3d 170 (N.D.N.Y. 2014) is invalid. This argument is meritless.

The Court need not address the "law school 101" issue of whether, hypothetically, an interpretation of New York common law by the Arizona Supreme Court could invalidate the Northern District of New York's ruling about New York common law based, in part, on New York State Appellate Division case law. This is because a plain review of the decision in *Conklin* reveals that the Supreme Court of the State of Arizona did not address New York common law or the *Rosen* decision. And, while the *Conklin* court disagreed with the 9th Circuit's interpretation of Arizona common law in *Stengel v. Medtronic Inc.,* 704 F.3d 1224 (9th Cir. 2013), which was referenced in *Rosen*, *Rosen* was not -- as defendant disingenuously argues -- "significantly predicated on *Stengel*."[1] Rather, the holding in *Rosen* was predicated on an interpretation of New York common law.

In the case at bar, plaintiff brings his claims not under federal law, but for violation of the parallel requirements of New York common law. In *Baker v. St. Agnes Hosp.,* 70 A.D.2d 400, 421 N.Y.S.2d 81 (App. Div. 1979), the mother of an infant injured by defendant's drug filed an

[1] Plaintiff disagrees with defendant's argument about *Conklin*'s impact on the viability of *Michajlun v Bausch & Lomb, Inc.* 2015 U.S. Dist. Lexis 30024 (S.D. Cal. Mar. 11, 2015) for the same reason.

action seeking damages from the drug manufacturer on theories of common law strict liability and negligence. Defendant argued that its package inserts adequately warned of the drug's dangers and that the doctor's failure to consult reference material on the drug before prescribing it was the proximate cause of the infant's injuries. The Appellate Division denied defendant's motion for summary judgment and indicated that under New York common law, a drug manufacturer is "under a duty to warn the medical profession of dangers inherent in its biological drugs which, in the exercise of reasonable care, it knew or should have known to exist." And, "it must keep abreast of knowledge of its products as gained through research, adverse reaction reports, scientific literature and other available methods;" and "equally important, it must take such steps as are reasonably necessary to bring that knowledge to the attention of the medical profession. The greater the potential hazard of the drug, the more extensive must be the manufacturer's efforts to make that hazard known to the medical profession." Id. at 82. The *Baker* court also provided examples of what defendant could have done to discharge its duty under New York common law, i.e. "dear Doctor" letters addressed to physicians, notices in medical journals, and calling physicians personally to present them with information. Id. at 86.

Thereafter, in *Rosen v. St. Jude Med., Inc.,* 41 F. Supp. 3d 170 (N.D.N.Y. 2014), where plaintiff alleged that she suffered injuries as a result of defects associated with a Class III medical device and asserted a failure to warn claim, the Court cited *Baker* to describe the duty of a medical device manufacturer under New York common law. The Court then held that because plaintiff alleged a violation of a federal regulation, and New York imposes a similar state duty, plaintiff's failure to warn claim was "parallel" and not "different or in addition to" the applicable requirements under federal law. Id. at 183-185.

Similarly, in the case at bar, plaintiff is asserting that had defendant complied with 21 CFR § 803.50 by communicating adverse event reports to the FDA, defendant would have effectively warned surgeons, including plaintiff's surgeon, of those adverse events. This is because events which are reported to the FDA are input into the MAUDE system, which is available to medical professionals and the public at large. Defendant's failure to communicate adverse event reports to the FDA -- which is required under federal law -- amounted to a breach of the parallel, New York common law duty as enunciated by, *inter alia*, *Baker* and *Rosen*. Notably, in a September 28, 2018 opinion in *A.F. v. Sorin Grp. USA, Inc.,* 2018 U.S. Dist. LEXIS 168726 (S.D.N.Y. Sep. 28, 2018) -- where plaintiff alleged defendant failed to timely report adverse events to the FDA -- the Southern District of New York partially denied defendant's motion to dismiss, indicated that it "agree[d] with Judge Kahn's decision in *Rosen*," and explained:

> Under New York common law, a "manufacturer of a product used by the medical community has a duty to warn the medical community 'of all potential dangers which it knows or should know, and must take such steps as are reasonably necessary to bring that knowledge to the attention of the medical [community].'" *Clar v. Riegler*, 46 A.D.3d 1465, 849 N.Y.S.2d 739, 740 (App. Div. 4th Dep't 2007) (alteration in original) (quoting *Glucksman v. Halsey Drug Co.*, 160 A.D.2d 305, 553 N.Y.S.2d 724, 726 (App. Div. 1st Dep't 1990)). "This duty is a continuous one, and requires that the manufacturer be aware of the current information concerning the safety of its product." *Krasnopolsky v. Warner-Lambert Co.*, 799 F. Supp. 1342, 1345-46 (E.D.N.Y. 1992) (citing *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 91 (2d Cir. 1980)). Moreover, New York courts have long recognized that the violation of a regulation mandating a standard of conduct is some evidence of negligence and probative of whether the conduct is reasonable and adequate under the circumstances. *E.g., Rizzuto v. L.A. Wenger Contracting Co.*, 91 N.Y.2d 343, 693 N.E.2d 1068, 1072, 670 N.Y.S.2d 816 (N.Y. 1998)…Accordingly, the Court holds that a manufacturer's duty to take steps that are reasonably necessary to warn the medical community may include warning the FDA as required by the MDA. Id. at 14-16.

For these reasons, and the reasons articulated in prior submissions and during oral argument, plaintiff respectfully asserts that -- even upon consideration of the *Conklin* decision -- defendant's motion to dismiss must be denied.

DATED: January 16, 2019

Respectfully submitted,
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By:_____

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